



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/878,034	06/08/2001	Daniel McTeigue	MCP-0279	1620

27777 7590 02/27/2006

PHILIP S. JOHNSON
JOHNSON & JOHNSON
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

EXAMINER

YEBASSA, DESTA LETTA

ART UNIT	PAPER NUMBER
----------	--------------

1615

DATE MAILED: 02/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/878,034

Applicant(s)

MCTEIGUE ET AL.

Examiner

Desta L. Yebassa

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449/PTO/SB/08)
Paper No(s)/Mail Date 01/09/2006; 5/5/05

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Continued Prosecution Application

A request for continued examination under 37 CFR 1.114 was filed in this application after a decision by the Board of Patent Appeals and Interferences, but before the filing of a Notice of Appeal to the Court of Appeals for the Federal Circuit or the commencement of a civil action. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 05/05/2005 has been entered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 4-6, 9-12, 14-16, 19 and 22-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Mehta et al. (U.S. Patent No. 5,084,278).

Mehta et al disclose taste-masking microcapsules with a core containing active agent and a polymeric coating comprising (a) an enteric polymer, and (b) a water-

insoluble film-forming polymer. See (column 4, line 1 –62). See (column 7, line 50) for acetaminophen, see (column 10, line 50-58 for claim 9 limitation. The polymeric coating, the active ingredient are the same, it is expected to have the same dissolution rate when tested according to USP method II at 50 rpm using the claimed buffer.

Claim Rejections - 35 USC § 102

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-6, 8,11-16, 17,and 19-24 are rejected under 35 U.S.C. 102(e) as being anticipated by Friend et al. (U.S. Patent No. 6,139,865).

Claim 1 is drawn to a taste-masked particle comprising a core containing an active ingredient and a polymeric coating. Friend et al. disclose a taste masked microcapsule composition that may be any pharmaceutical formulations such as chewable tablets, effervescent tablets, powders, liquids dispersions comprises microcapsules of drug and water-insoluble polymeric material typically a cellulosic

Art Unit: 1615

polymer and the drug is coated by polymeric materials (abstract); a drug may include any active ingredients such as antibiotics, analgesics, anti-inflammatory agent and the like (column 4, lines 15-35). Friend et al. also disclose a polymeric material such as ethyl cellulose, hydroxypropyl methyl cellulose phthalate, cellulose acetate and the like which are effective to microcapsulate the drug, water insoluble, an enteric polymer and provides effective taste masking of the drug (column 7, lines 25-40). The specification does not define the scope for "substantially free" claims 2-3 are also anticipated, since the surface of the particle is free of plasticizer and active ingredient. The polymeric coating, the active ingredient are the same, it is expected to have the same dissolution rate when tested according to USP method II at 50 rpm using the claimed buffer.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mehta et al. (U.S. Patent No. 5,084,278) in view of Friend et al. (U.S. Patent No. 6,139,865) and Morella et al (Canadian application No 2,068,366).

Mehta et al and Friend et al. would applied as have been discussed above.

Mehta et al and Friend et al do not teach additional water-soluble polymer (claim 7).

However, Morella et al. disclose a taste masked free flowing powder including microcapsules, wherein each microcapsule includes an effective amount of a core element including at least one pharmaceutically active ingredient, a substantially smooth and continuous microcapsule coating on the core element formed from a coating composition including a water insoluble polymer (.p 25, claim 1). Morella et al. teach that this polymer is ethyl cellulose (p 25, claim 7). Furthermore, Morella et al. teach that the active agent can be a non-steroidal anti-inflammatory agent (p 25, claim 5). Morella et al. also teach the tasted masked free flowing powder composition discussed above, wherein the coating composition includes a water insoluble polymer (ethyl cellulose) and a polymeric component which can be an enteric polymer (p 26,claim 9). In their disclosure, Morella et al. teaches that enteric polymers include cellulose acetate phthalate, hydroxypropyl methyl cellulose phthalate, hydroxypropyl methyl cellulose acetate and others (p 9, lines 30-38). Additionally, Morella et al. teach that the coating comprises a water insoluble polymer, and one or more of an enteric polymer, an acid-soluble polymer, and a partially water-soluble polymer (p 26, claim 9). The reference also allows for the inclusion of water-soluble polymer at (page 10, lines

Art Unit: 1615

11-19). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the composition of Mehta et al. or Friend et al. and add water-soluble polymer taught by Morella et al. One of ordinary skill in the art would be motivated to add water soluble polymer in to composition of Mehta et al. or Friend et al. with the reasonable expectation of success that the coated microcapsule or particles exhibit reduced dissolution profile.


Telephonic Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Desta L. Yebassa whose telephone number is 571-272-8511. The examiner can normally be reached on Monday to Friday 8.00 am –6.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Desta L. Yebassa, PhD
Patent Examiner


JYOTHSNA VENKAT
PRIMARY EXAMINER
GROUP 1500-16W